BAYCARE Institutional Review Board **POLICY/PROCEDURE**

TITLE: Investigator Conflict of Interest Policy	**POLICY NUMBER:** IRB-E14W61
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ISSUED FOR: All BayCare, Investigators, Research Personnel **SPONSORED BY:** BayCare Institutional Review Board	**ORIGINAL ISSUE DATE:** 04/89 **REVISION DATE:** 12/98, 07/15, 11/16, 02/17, 01/19 **REVIEW DATE:**
APPROVED BY: BayCare Health System (BCHS) Institutional Review Board (IRB	

To describe the policies and procedures for identifying and managing any significant financial interest held by Investigators (as defined below) that could affect research involving human subjects.

PURPOSE:

The BayCare Health System is committed to conducting all research activities in accordance with the highest standards of integrity and ethics. Institutional regulations **(E14W61A Financial Conflicts of Interest in Research)** set forth principles, policies, and procedures to ensure that Investigator financial interests do not compromise the objectivity with which the Investigator designs, conducts, and reports the research. These regulations apply equally to all research whether the study is funded or non-funded. The Institutional Review Board is the administrative unit that manages the BayCare individual conflict of interest policy.

The BayCare Institutional Review Board (IRB) has established procedures to ensure that Investigator financial interests do not affect the rights and welfare of human subjects in research. IRB policy requires that Investigators report all significant financial interests on each study to the IRB for review to assure protection of the rights and welfare of human subjects participating in research.

DEFINITIONS

Investigator: as defined by E14W61A Financial Conflicts of Interest iri Research means the project director or principal investigator/program director, co-investigator, collaborator, senior/key personnel, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research.

A potential or actual Conflict of Interest: (COI) exists when a significant financial interest (as defined below) of an Investigator or a family member of the Investigator could directly and significantly affect the design, conduct, or reporting of research

Significant Financial Interest: means a financial interest consisting of one or more of the following interests of an Investigator or family member that reasonably appears related to the individual's institutional responsibilities:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000;

- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity during the 12 months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator or family member holds any equity interest in the entity;
- A significant financial interest includes any intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;
- For an Investigator who applies for or receives funding through a Public Health Service (PHS) grant, cooperative agreement, or contract, a significant financial interest includes any reimbursed or sponsored travel (i.e., paid on behalf of the investigator rather than being reimbursed) that reasonably appears related to their institutional responsibilities. Excluded *is travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education defined as an academic teaching hospital, or a medical center or a research institute that is affiliated with an institution of higher education.*

The term, for human subjects' research, does *not* include:

- Salary or other remuneration from your institution;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency;
- Income from service on advisory committees or review panels for a federal, state, or local government agency.

POLICY:

Included with a new submission and yearly continuing review investigators must include signed Conflict of Interest (COI) Forms. There should be a separate form for PIs, Sub-Is, and research personnel.

PROCEDURE:

Disclosure Requirements for Externally and Internally Funded Research

1. All Investigators conducting externally or internally funded research must complete the *Financial Disclosure Form (FDF),* disclosing any significant financial interest, prior to submission of a proposal for external funding or participating in any research activity regardless of the source of funding, as defined in E14W61A Financial Conflicts of Interest **in** Research. The Investigator must complete an FDF at least annually or within 30 days of acquiring a new financial interest that reasonably appears related to his or her institutional responsibilities.

2. The FDF contains questions designed to determine whether the Investigator or anyone in his/her immediate family has significant financial interests which could impact the objective pursuit of the research.

3. The Conflict of Interest Committee reviews the completed FDF and refers any potential financial conflict of interest to the Institutional Official (IO) or *the senior Institutional administrator.*

Disclosure Requirements for Non-funded Research

1. If the study is not funded, the Principal Investigator (PI) may not have completed the FDF prior to IRB submission.

2 .The PI conducting non-funded research completes the question regarding financial interest in the IRB application for all investigators

3. If the PI answers the question indicating that he/she or another investigator involved with the project has a significant financial interest requiring disclosure, the PI or the investigator with the conflict completes the FDF.

4. The IRB Office will notify the Conflict of Interest Committee of the Financial Disclosure Form to be reviewed.

5. The Investigator must complete an FDF at least annually or within 30 days of acquiring a new significant financial interest that reasonably appears related to his or her institutional responsibilities.

Review of Disclosures and Management of Conflicts

1. The Conflict of Interest Committee reviews the FDF to assess whether or not the significant financial interest constitutes a financial conflict of interest. The conflict of Interest committee which includes the IO may involve the Investigator in the determination of whether a disclosed significant financial interest is related to the Investigator's research.

2. If the review reveals that the disclosed significant financial interests do not represent a financial conflict of interest, the determination is recorded and no further action is required.

3. If a potential financial conflict of interest exists, the IO notifies the Investigator and the appropriate *Institutional Administrator/department chair.*

4. The IO and *Institutional Administrator/department chair* reviews the Financial Disclosure along with the Investigator to determine if the Investigator can eliminate the conflict. If the Investigator can eliminate the conflict, the Institutional Administrator/department chair provides a written copy of the agreement to the IO or designee and, if the IO or designee approves the plan, no further action is needed.

5. If the Investigator cannot eliminate the conflict, the Investigator proposes a plan to manage or reduce the conflict. If the research involves human subjects, the Investigator must design the plan so that the financial interest does not affect the risk to or welfare of research subjects. The IO reviews the plan and refers the case to the Conflict of Interest Committee (COIC) for review.

6. The COIC may accept the recommended plan, add to it, or create a new plan. As outlined in E14W61A Financial Conflicts of Interest in Research. The COIC has broad discretion to

recommend a variety of conditions to manage, reduce, or eliminate the conflict. The COIC sends its recommendations to the IO.

7. The IO may accept the recommendation or modify the proposed plan. The IO makes the final decision to approve a management plan.

IRB Review of the Approved Management Plan

1. The IRB does not complete its review and approval of the IRB application until it receives the final approved management plan. Upon receipt of the plan from COIC, IO presents the plan to the IRB. The IRB reviews the plan using either the convened IRB or expedited procedures based upon whether the study is eligible for expedited review.

2. The IRB determines whether the conditions in the approved plan for managing the financial interest adequately protect the rights and welfare of human subjects or whether additional actions are necessary to minimize the risks to subjects. The IRB determines the kind, amount, and level of detail of information the PI must provide to subjects in the informed consent process regarding source of funding, funding arrangements, financial interests of parties involved in research, and any techniques applied to manage financial COI.

3. The IRB has the final authority to decide whether the interest and management, if any, allows the research to be approved. The IRB may impose further restrictions on the protocol or disapprove the protocol. The IRB does not have the authority to disapprove the final IO approved management plan but may require additional protections for human subjects before the research can be initiated.

Sponsor-Investigator Clinical Trials

1. If the PI is also considered the sponsor who holds an investigational new drug (IND) or an investigational device exemption (IDE), he/she follows Food and Drug Administration (FDA) requirements for reporting financial disclosures as outlined in 21 CFR 54.